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EXAMINER

GAKH, YELENA G

ART UNIT

PAPER NUMBER

1743

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/940,518	LIM ET AL.
	Examiner	Art Unit
	Yelena G. Gakh, Ph.D.	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 29 August 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 35-77 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 35-77 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 29 August 2001 is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) Other: _____

DETAILED ACTION

1. The instant application is co-pending with US Application Ser. No. 10/29,1689. According to the Preliminary Amendment, claims 35-77 are pending in the Application. Claims 1-34 and 78-103 are cancelled without prejudice.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 76 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites, “said indicator *includes* a detection limit of at least 0.5 µg of acetaldehyde”. The language of the claim is not clear. Does it actually mean that the indicator *has* “a detection limit”? Also, it is not clear, what such detection limit means – that there should be at least 0.5 µg of acetaldehyde present in order to be detected? Does it mean that the volume in which this amount is present does not matter? Is this a lower detection limit, beyond which the indicator does not work? What then is the sense for such limitation? The language of the claim renders it unclear and indefinite.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. **Claims 35, 37-38, 40-41, 47-48, 51, 53-54, 63-64 and 67** are rejected under 35 U.S.C. 102(b) as being anticipated by Iannacone et al. (US 3,645,696).

Iannacone discloses "a method for the preparation of a chromogenic reagent for aldehydes which is normally unstable upon exposure to air. The invention comprises the dissolving of the chromogenic reagent in a solvent and subsequently pouring the solvent containing the dissolved chromogenic reagent onto a support medium [carrier], while constantly in the presence of an inert atmosphere. The support medium may be dried simultaneously with the adsorption of the chromogenic reagent. Some chromogenic reagents, which may be utilized, are salicylalhydrazone, p-nitrobenzalhydrazone, 2-hydrazinobenzothiazole, 2-hydrazinobenzothiazole-4-nitrobenzenediazonium fluoborate, etc., while **3-methyl-2-benzothiazolinone hydrazone hydrochloride monohydrate (MBTH)** is preferred. One of the solvents used to dissolve the chromogenic reagent to further its introduction onto the support medium is deionized and/or distilled **water**, while **any solution, which will dissolve the test reagent**, may be utilized. The support medium may consist of **any suitable material** such as anhydrous **aluminum, silica gel, diatomaceous earth, firebrick or polymeric material**. Suitable polymeric material includes polyethylene, nylon, etc. and is preferably present **in particulate form** such as chips or **powder**. The inert atmosphere may be provided such as by introducing a **continuous flow of dry nitrogen** gas through the support medium during the adsorption period. The drying process is generally conducted at a **temperature less than about 100 °C** during the entire preparation of the chromogenic reagent material" (col. 2, lines 5-38). "The MBTH solution in deionized water would generally be a **0.5 to 5 percent solution**" (col. 3, lines 43-45). The carrier, which is a support, is inert to the aldehyde-reactive reagent.

6. **Claims 35-36, 40-42, 44-45, 47-49, 52, 53-54 and 62-66** are rejected under 35 U.S.C. 102(b) as being anticipated by Moore (US 5,332,548).

Moore teaches a method for preparation of "an analytical device for detecting a gaseous or volatile analyte emitted or released from a solid material, and is adaptable to be applied directly to or in contact with a surface of the solid material. The device comprises (a) a substrate for adjacent disposition on a surface of the solid material from which the analyte is emitted, said substrate being substantially inert to the analyte, (b) an analyte-reactive component, and (c) an indicator" (col. 4, lines 6-13). "Although the invention is described with particular reference to

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detecting or determining **formaldehyde** emissions, it should be understood that the invention is also applicable to other gaseous or volatile analytes which meet the criteria of the invention, as for example, isobutane, acetone, butyl acetate, methyl acrylate, isopropyl acetate, methyl ethyl ketone, diisobutyl ketone, **acetaldehyde**, etc." (col. 7, lines 40-47).

"In a preferred embodiment, the substrate comprises a planar strip of high purity paper ... cut from a mother web or roll. Thus, the mother roll can be coated or impregnated first with the analyte-reactive component, as by spraying, dipping, brushing, spreading, printing, etc., and then dried in air or preferably in an **inert or non-interfering atmosphere such as nitrogen**, and/or **dried in a low temperature oven** of from about 25° to 90° C, which in any case may be conducted under **reduced pressure**, although the drying temperature can be higher depending largely on such factors as type of substrate, composition and concentration of the reagent, and drying time. The indicator coating is next applied in a similar manner" (col. 8, lines 28-48).

→ "Suitable substrate materials include natural and synthetic materials, such as cellulose (e.g., wood cellulose, cotton, and rayon), **polyolefins** (e.g., polyethylene, and polypropylene), nylon, **glass fibers**, and **ceramic-type materials**" (col. 8, lines 8-11). "Synthetic materials include synthetic papers, nonwoven polyolefins, glass fibers, glass **beads**, and such materials as **silica gel**, activated **alumina**, and molecular sieves **applied as a thin coating on an inert carrier** [support] which preferably is transparent such as polyethylene tape" (col. 8, lines 20-25).

"The analyte-reactive component is applied to **at least a portion of the substrate** typically as a **solution** as by dipping, spraying, spreading, brushing, or printing" (col. 8, lines 66-68). The adhesive polyethylene tape can be single or double sided depending on the embodiment, as disclosed in column 11.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claim 39** is rejected under 35 U.S.C. 103(a) as being unpatentable over Iannacone or Moore in view of e.g. Cohen et al. (US 3,649,159).

Iannacone or Moore does not particularly disclose optimizing pH of solution for promoting solubility of an aldehyde-reactive reagent. However it is well-known that solubility of many organic compounds, which are not completely dissolved in water, such as dyes, depends on pH of the solution, as indicated e.g. by Cohen: "in many instances, the optimum pH is dependent upon the solubility of the dye material" (col. 4, lines 30-31).

It would have been obvious for anyone of ordinary skills in the art to optimize pH of the solution to promote solubility of an aldehyde-reactive reagent, since in many instances it is a dye, which is not completely dissolved in water, as indicated by Cohen.

11. **Claims 43, 46 and 50** are rejected under 35 U.S.C. 103(a) as being unpatentable over Iannacone or Moore in view of the well known prior art, e.g. Meier et al. (EP 885914 A2, Abstract).

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Although Iannaccone or Moore does not specifically indicate a membrane, foam and kaolin, it would have been obvious for anyone of ordinary skills to use a membrane, foam or kaolin as suitable carriers, since polymeric membranes and foams are well known conventional carriers along with gels and films, as indicated e.g. in Meier: "gels, films and foams may have an extremely high water uptake capacity" (see Advantage), and kaolin (alumina silicate) is a part of ceramic materials indicated by Moore.

12. **Claims 55-61** are rejected under 35 U.S.C. 103(a) as being unpatentable over Iannaccone or Moore in view of the well-known prior art, indicated e.g. in Jilla (US 3,932,126).

Although Iannaccone or Moore does not disclose various sources of heat recited in claims 55-61, it would have been obvious for anyone of ordinary skills in the art to use any controllable sources of heat for drying the reagent, such as disclosed e.g. in Jilla: "the initial drying of impregnated polyester material may be carried out in any convenient equipment per se well known in the art, such as a **dielectric heater, a microwave heater, an infrared heater**" (col. 2m lines 35-38), since only controlled temperature is important for the correct conditions of drying so as not to degrade the reagent. A water bath is known to give temperatures less than 100° C, which is in the range disclosed by Iannaccone and Moore.

13. **Claims 68-71 and 74, 76-77** are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore in view of Wang (US 4,622,207).

Moore teaches a method for preparation of "an analytical device for detecting a gaseous or volatile analyte emitted or released from a solid material, and is adaptable to be applied directly to or in contact with a surface of the solid material. The device comprises (a) a substrate for adjacent disposition on a surface of the solid material from which the analyte is emitted, said substrate being substantially inert to the analyte, (b) an analyte-reactive component, and (c) an indicator" (col. 4, lines 6-13). "Although the invention is described with particular reference to detecting or determining formaldehyde emissions, it should be understood that the invention is also applicable to other gaseous or volatile analytes which meet the criteria of the invention, as for example, isobutane, acetone, butyl acetate, methyl acrylate, isopropyl acetate, methyl ethyl ketone, diisobutyl ketone, **acetaldehyde**, etc." (col. 7, lines 40-47).

"Synthetic materials include synthetic papers, nonwoven polyolefins, glass fibers, glass **beads**, and such materials as silica gel, activated **alumina**, and molecular sieves **applied as a**

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thin coating on an inert carrier which preferably is transparent such as polyethylene [adhesive] tape" (col. 8, lines 20-25). The mean emission rate moles detected by the indicator are 0.5×10^{-8} – 1.9×10^{-6} $\text{CH}_2\text{O}/\text{cm}^2/\text{hr}$.

Moore does not specifically disclose bonding the adhesive tape with a thin layer of the coated particulate carrier to a support.

Wang describes "a typical construction of a reagent device employing filter paper as the carrier matrix material", wherein a carrier matrix with a reagent is affixed by means of "double faced adhesive tape 16 to an insoluble support member, such as organoplastic strip 18" shown in Figure 1 (col. 5, lines 31-35).

It would have been obvious for anyone of ordinary skills in the art to modify a method of making indicator taught by Moore by adding a step of bonding the adhesive tape with a thin layer of the coated particulate carrier to a support the way it is indicated by Wang, because it is a simple and conventional structure of a test strip reagent device.

It would have been obvious for anyone of ordinary skills to use one-sided tape for the same purpose and attach it to the support with additional means, e.g. another adhesive tape.

14. **Claims 72-73** are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore in view of Wang, as applied to claims 68-71 and 74-77 above, and further in view of Iannacone.

Moore in view of Wang does not specifically teach dissolving 3-methyl-2-benzo-thiazolinone hydrazone hydrochloride monohydrate (MBTH) in water with the concentration of MBTH between 0.5-3%.

Iannacone teaches "a method for the preparation of a chromogenic reagent for aldehydes" which involves 3-methyl-2-benzo-thiazolinone hydrazone hydrochloride monohydrate (MBTH) water solution with 0.5 to 5% weight range.

It would have been obvious for anyone of ordinary skills in the art to make the indicator as disclosed by Moore in view of Wang, specifically with MBTH reagent applied at 0.5 to 5% weight range, since Iannacone disclosed such reagent for detecting acetaldehyde, which is one of the analyte gases indicated by Moore.

15. **Claim 75** is rejected under 35 U.S.C. 103(a) as being unpatentable over Moore in view of Wang, as applied to claims 68-71 and 74-77 above, and further in view of Manning et al. (US 4,946,705).

Moore in view of Wang does not specifically teach that alumina particles are less than 180 μm in size.

Manning discloses "a simple, inexpensive, and versatile device for measuring gaseous substances and a method for manufacturing of such devices" (Abstract). The device comprises a reflectant baking on which are disposed microparticles coated at the surface with a reagent. "Suitable microparticulate adsorbents are particulate solids which have surface areas of at least $10 \text{ m}^2/\text{g}$, preferably $100-1000 \text{ m}^2/\text{g}$. These materials usually have a particle size of 100 microns or less, i.e., **0.1-100 microns**. Materials which are available in this form include inorganic refractory oxidic supports, such as **alumina**, silica, glass, titania, **clays** and the like, or organic polymers which have been treated to achieve porosity, e.g., porous cellulose, polypropylene, and polystyrene-divinylbenzene particles. In order to be compatible with a detection reaction which generates color the support must be essentially colorless" (col. 7, lines 52-60). Therefore, ""microparticulate" support refers to particles which are reflectant, and finely divided so as to expose a large amount of surface area for coating with collection layers. **The size of the particles is inversely proportional to the sensitivity of the device, since more surface area imparts more sensitivity to the test.** Sizes of particles in the range capable of providing $10-1000 \text{ m}^2/\text{g}$ are suitable for uses in the invention, but this range is not taken to be limiting. Larger particle sizes are workable but decrease the sensitivity. Smaller particles are desirable from the standpoint of sensitivity but may be less convenient to handle. Any workable surface area/mass ratio is within the scope of the invention, and the suggested range is merely intended to provide guidance to practitioners thereof" (col. 4, lines 60-69).

It would have been obvious for anyone of ordinary skills in the art to use alumina particles of size less than 180 μm , in particular of the size range of 0.1-100 microns for the same reason emphasized by Manning, i.e. to increase the surface area for coating and therefore increase the sensitivity of the indicator.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (703) 306-5906. The examiner can normally be reached on 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Yelena G. Gakh

April 23, 2003

A handwritten signature in black ink, appearing to read "Yelena Gakh".